UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,288	03/10/2004	Marlene M. Darfler	26204-002US	9373

61263 7590 07/01/2008

PROSKAUER ROSE LLP
1001 PENNSYLVANIA AVE, N.W.,
SUITE 400 SOUTH
WASHINGTON, DC 20004

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
07/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,288	DARFLER ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9-12,14-17,40 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 9-12, 14-17 and 40-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Request for continued examination (i.e., R.C.E.) under 37 C.F.R. §1.114, including the fee set forth in 37 C.F.R. §1.17(e), was filed in this application on 09 April 2008 after a Final action mailed on 25 February 2008. Since this application is eligible for continued examination under 37 C.F.R. §1.114, and the fee set forth in 37 C.F.R. §1.17(e) has been timely paid, the finality of the previous Office action mailed 25 February 2008 has been withdrawn pursuant to 37 C.F.R. §1.114. Applicants' submission filed 09 April 2008 has been entered. Accordingly an R.C.E. has been established and the action on R.C.E. follows.

2. Response filed 09 April 2008 to the Office Action mailed 25 February 2008 is acknowledged and entered.

3. Declaration of Ms. Marlene Darfler under 37 C.F.R. §1.132 filed 31 October 2007 is re-considered in view of the applicants' arguments presented in the response filed 09 April 2008..

Withdrawals in View of Amendments and Remarks

4. In view of amendments and remarks filed 09 April 2008, and reconsideration of Ms. Marlene Darfler's Declaration under 37 C.F.R. §1.132 filed 31 October 2007 the following rejections in the Office Action mailed 25 February 2008 are hereby withdrawn:

- The rejection to Claims 1-4 and 7-17 under 35 U.S.C. §102 (b) as anticipated by Banerjee et al (Biotechniques, 1995, from Applicants' IDS); and
- The rejection to Claims 1-17 under 35 U.S.C. §102 (b) as anticipated by Wang et al (US Patent 5,672,696, issued 30 September 1997, from applicants' IDS dated 29 May 2007).

Claims Status

5. Claims 5-8, 13 and 18-39 have currently been cancelled.

6. Claims 40-41 have been added.

7. Claims 1-3 and 17 have been amended.

8. Claims 1-4, 9-12, 14-17 and 40-41 are pending and are examined on merits.

Claims Objection

9. Claims 9-10, 15-16 and 40 are objected to for following reasons:

- Claims 9-10, 16 and 40 are objected to because at Line one of each one of the cited Claims, before the word "wherein" a --, -- should be inserted. Appropriate correction is required.

- Claim 15 is objected to because at Line one of the cited Claim, before the word "further" a --, -- should be inserted. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

First Paragraph Rejections

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

11. Claims 1-4, 9-12, 14-17 and newly presented Claims 40-41are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The M.P.E.P. states that the purpose of the written description requirement is to ensure that the inventor had possession; at the time the invention was made, of the specific subject matter claimed. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. *In* Regents of the University of California v. Eli Lilly & Co. the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Fiers, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or sub-combinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

M.P.E.P. §2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." M.P.E.P. §2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See M.P.E.P. §2163. Although the M.P.E.P. does not define what constitutes a sufficient number of representative species, the courts have indicated what does not constitute a representative number of species to adequately describe a broad generic. In Gostelli, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are:(1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." (M.P.E.P. §2163).

In the instant case, Claims recite a method to prepare a biomolecule lysate through the steps of:

(a) heating a composition comprising a chemically fixed biological sample;

(b) heating said sample and a reaction buffer for a given time at a given temperature to reverse /release protein cross linking in said biological sample;

(c) subsequently, treating the resultant composition with a protease enzyme to disrupt the tissue and cellular structure of said biological sample;

(d) obtain said biomolecule lysate in a soluble liquid form, wherein contents of said biomolecule lysate are representative of the total protein content of said chemically fixed biological sample; and

(e) said biomolecule lysate is suitable for protein expression analysis.

Additional claims depending from the independent claim are drawn to homogeneous population of tissue or cells in said biological sample, manual mixing to mechanically disrupt said sample, the heating temperature within the range of 80 °C -100 °C for 10 mins to 4 hours, proteolytic enzyme treatment for 30 mins to 24 hours at 37 °C-65 °C, buffer is Tris at a pH of 6.0-9.0, additionally comprising a detergent, subsequent fractionation of biomolecule lysate in to distinct and separate biomolecules for biochemical assay.

The claimed invention is assessed as follows with regard to the written description factors listed *supra*.

(a) Level of skill and knowledge in the art:

At least a Bachelor Degree in Biochemical engineering, Biochemistry, Biology, Biomedical engineering, Biophysics, Chemical engineering, Chemistry, Environmental engineering, Environmental Science and Technology, Material science and engineering, Microbiology, Molecular biology, Pharmaceutical Sciences, or Pharmacology.

(b) Partial structure:

The structure of the claimed invention does not fit the description presented in currently written description because e.g., while formalin fixed biological samples are recited at Page 1, Lines 25-34 of the currently presented specification and further there is mention of "chemical fixative" on the same page; in the specification as currently presented, there is no description of chemically fixed biological sample. Furthermore, while "organic solvents" are defined at Page 12, Lines 16-17 of the specification, in the specification as currently presented, there is no precise description of removing paraffin in said biological sample by "adding an organic solvent". If such a showing exists in the specification as currently presented, it should be clearly made of record.

c) Physical and/or chemical properties:

The physical and chemical aspects for chemically fixed biological sample , or organic solvents to remove paraffin from said biological samples is not of record in the specification as currently presented. If such a showing exists in the specification as currently presented, it should be clearly made of record.

(d) Functional characteristics:

The structure-function relationships of chemically fixed biological sample , or organic solvents to remove paraffin from said biological samples is not of record in the specification as currently presented.

(e) Method of making the claimed invention:

As pointed out *supra*, in items b-d the description as presented in the currently presented specification does not give detailed information regarding chemically fixed biological sample, or organic solvents to remove paraffin from said biological samples. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984). Accordingly, it is deemed that the specification fails to provide adequate written description for the claims.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the claims because Claim 1 is the generic claim, and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

35 U.S.C. § 112, Second Paragraph Rejection

12. In view of the amendments filed 09 April 2008, following is indefiniteness rejection to Claim 15 and newly presented Claims 40-41.

13. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> ***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

14. Claims 15 and newly presented Claims 40-41are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- In Claim 15 is recited the limitation "said multi-use biomolecule lysate". There is insufficient antecedent basis for this limitation in claim 15 because Claim 15 is dependent from Claim 1 and claim 1 is not drawn to a method to prepare a "biomolecule lysate".

- Phrase, "drip column fractionation" renders Claim 40 incomprehensible, unclear and vague, because metes and bounds for the phrase, "drip column fractionation" are not defined in

either the claim or the specification. Accordingly, a person of ordinary skill will not be able to understand the claimed invention.

- In Claim 41 is recited the limitation "further comprising assaying said lysate using mass spectrometry". There is insufficient antecedent basis for this limitation in claim 41 because Claim 41 is dependent from Claim 1and claim 1 is not drawn only to a method to prepare a "biomolecule lysate".

Conclusion

15. For reasons aforementioned, no Claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

25 June 2008
/David M. Naff/
Primary Examiner, Art Unit 1657